PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, October 28, 2003, 10:00 a.m., Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts. Public Health Council Members present were: Chair Christine Ferguson, Mr. Manthala George, Jr., Ms. Maureen Pompeo, Mr. Albert Sherman, Ms. Janet Slemenda, Dr. Thomas Sterne, Mr. Gaylord B. Thayer, Jr., and Dr. Martin Williams. Ms. Phyllis Cudmore was absent. Attorney Donna Levin was present as General Counsel and Attorney Susan Stein as Acting General Counsel.

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Chair Christine Ferguson announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A ½. In addition, Commissioner Ferguson announced the appointment of a new member Mr. Gaylord B. Thayer, Jr. of Wellesley Hills, MA. Mr. Thayer is a seasoned global technology executive and Boston area angel investor. He serves on the Board of Directors of the American Cancer Society's New England Division and is a member of the board's Management Compensation Committee, Outcomes Committee and chairs the Awards Committee. Mr. Thayer is a member of the Finance Committee of the Osteogenesis Imperfecta Foundation. He is also an elected Town Meeting Member for the town of Wellesley. In addition, he is an Executive in Residence on the faculty of Babson College in Wellesley, MA.

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The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Ms. Nancy Ridley, Assistant Commissioner, Bureau of Health Quality Management; Dr. Paul Dreyer, Director, Division of Health Care Quality; Ms. Anne Sheetz, Director, School Health Services; Mr. Brad Prenney, Acting Director, Division of Community Sanitation; Ms. Louise Goyette, Director, Office of Emergency Medical Services; Mr. Grant Carrow, Director, Drug Control Program; Ms. Joyce James, Director, Ms. Joan Gorga, Program Analyst, Determination of Need Program; and Attorney Howard Saxner, Deputy General Counsel, Office of the General Counsel.

PERSONNEL ACTIONS:

In letters dated October 8, 2003, Katherine Domoto, M.D., Associate Executive Director for Medicine, Tewksbury Hospital, Tewksbury, recommended approval of appointments and reappointments to the various medical staffs of Tewksbury Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Associate Executive Director for Medicine of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointments and reappointments to the various medical staffs of Tewksbury Hospital be approved for a period of two years beginning October 1, 2003 to October 1, 2005 as follows:

APPOINTMENTS	STATUS/SPECIALTY	MEDICAL LICENSE NO.
Patricia Pickett, M.D.	Active/Psychiatry	59253
Susan Walker, M.D.	Affiliate Psychiatry	216417
Jonathan Hertz, M.D.	Affiliate/Psychiatry	212535
David Wolff, Ph.D.	Allied/Psychology	8055

REAPPOINTMENTS	STATUS/SPECIALTY	MEDICAL LICENSE NO.
Philip Simkowitz, M.D.	Active/Psychiatry	152536
John Duggan, O.D.	Allied/Optometry	2186

In a letter dated October 20, 2003, Paul D. Romary, Executive Director, Lemuel Shattuck Hospital, Jamaica Plain, recommended approval of initial appointments and reappointments to the various medical staffs of Lemuel Shattuck Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Lemuel Shattuck Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the initial appointments and reappointments to the various medical staffs of Lemuel Shattuck Hospital be approved as follows:

APPOINTMENTS	STATUS/SPECIALTY	MEDICAL LICENSE NO.
Gregory Biedermann, M.D.	Consultant/Internal Medicine	218798
Bradley Deal, M.D.	Consultant/Psychiatry	217999
Mohamed Ayadi, M.D.	Consultant/Radiology	213617
Sanjeev Bagga, M.D.	Consultant/Radiology	216581
Joseph Santoro, M.D.	Consultant/Radiology	213293

ALLIED HEALTH PROFESSIONAL APPOINTMENT	STATUS/SPECIALTY	MEDICAL LICENSE NO
Sarah Bachrach	Allied Health Professional Department of Medicine	206

REAPPOINTMENTS	STATUS/SPECIALTY	MEDICAL LICENSE NO.
Shreekant Chopra, M.D.	Active/ Internal Medicine/Nephrology	3906
Kenneth Pariser, M.D.	Active/Internal Medicine /Rheumatology	40490
Arshanskiy Yevgenity, M.D.	Consultant/Radiology	204156
Inna Goldberg, M.D.	Consultant/Radiology	80298

Gregory Clark, M.D.	Active/Psychiatry	47684
Charles Hanson, M.D.	Consultant/Psychiatry	74077
David Tesini, D.M.D.	Consultant/Dentistry	12919

ALLIED HEALTH PROFESSIONAL REAPOINTMENT	**STATUS/SPECIALTY**	**MEDICAL LICENSE NO.**
Betty Morgan, R.N.	Registered Nurse/Psychiatry	148706

STAFF PRESENTATION: NO VOTE/INFORMATION ONLY

"MEDICAL ERRORS: TRENDS AND PATIENT SAFETY, A 2003 UPDATE", by Nancy Ridley, Assistant Commissioner, Bureau of Health Quality Management, and Paul Dreyer, Ph.D., Director, Division of Health Care Quality

Ms. Ridley said, "We are going to present a brief overview of where we stand from the standpoint of reporting of serious incidents and medical errors to the Department of Public Health, along with a number of the prevention initiatives the Department has been undertaking for the last couple of years, and I will give you a very brief history of what has happened in Massachusetts in the last few years, in particular, but I want to make one point that, in Massachusetts, the reporting of serious incidents or medical errors actually goes back to at least the early 1980s, where there has been a requirement for hospitals, nursing homes, and some other institutions to actually report to the Department of Public Health."

Ms. Ridley continued, "Probably the sentinel event that caught everybody's attention occurred for us in 1995. Actually, the death occurred at the end of 1994, of a Boston Globe columnist, Betsy Lehman, at the Dana Farber, from a chemotherapy overdose. That incident was discovered by the institution in early 1995 and reported to the Department of Public Health. That event sent a shot heard around the world as far as realizing that some of the most common problems can occur in our best institutions, and that the medical world needed to do something about patient safety and medical errors. The Coalition for the Prevention of Medical Errors was co-founded by the Department of Public Health in late 1996, and it culminated in our submission of a request to the Federal government for funding in late 2001. We received a fairly major patient safety grant. A piece of legislation was filed and approved by the legislature as part of the 2002 legislative season, and last year, I think, as most people know, resulted in the transfer of eight health boards over to the Department of Public Health for integration with other programs in the Department…"

Ms. Ridley further noted: "The Institute of Medicine, did a report in 1999 on patient safety that is considered to be the premier report. The report points out that three to four percent of all hospital admissions result in adverse events for patients, and that there are probably between 44,000 and 98,000 deaths each year from adverse events in this country. The estimate was between 17 and 29 billion dollars in cost both to the health care system and to the individuals

involved. About seven thousand of those deaths are actually attributable to medication errors, which is a high focus of priority.

Dr. Paul Dreyer, Director, Division of Health Care Quality, informed the Council about what is reportable under current DPH regulations. He presented a slide show. Some of the statistics he presented are: Data from 7/1/2002 through 6/3/03. "We have 757 hospital reports in that time period, and 571consumer complaints (may be some double counting). The largest category of hospital reports are falls. Almost exactly half of all hospital reports are falls and hospitals need only report serious injuries – falls that have serious consequences like a fracture…Consumers complained about the quality of nursing services, quality of medical care and other quality issues. Thirty-four percent of surgical events reported were retained objects, mostly sponges. Retained objects and the wrong side surgery make up more than half of surgical event complaints. In nursing homes, consumers complained of not being well attended by nursing staff. For example, "I rang the bell and nobody came for 20 minutes. Hospital site investigations increased from 1999 to 2003. The number has gone from about 125 to 225." Dr.Dreyer noted that this should not be looked at as an increase but rather the result of the Department hiring 25 new inspectors which increased the Department's ability to get on site and do an investigation.

Ms. Ridley, concluded the report with comments on the culture of blame versus the culture of safety. She said in part, "…We have been very fortunate to have in Massachusetts, a very educated health care industry and educated health care media that have done a fairly excellent job at portraying both sides of the issues in terms of what happens when something goes wrong at one of our institutions. We'd like to see a change in the culture within the institutions from one of fear to a culture of safety, where safety and patient care predominate. You also want to change the culture of denial, which is something that is very automatic, and inherent in many practitioners as well as institutional safety systems, to one of learning. You need to learn from the problems that you have experienced and you need to share those with others."

In addition, Ms. Ridley explained what DPH was doing with the AHRQ DPH Grant of four and a half million dollars awarded from the federal government two years ago. She said, "It is a patient and safety grant being used for four major projects involving the following: (1) creation of a web-based system for the Massachusetts reporting system instead of the present paper one; (2) development of best practices with the reconciliation of medications for patients as they transition from ambulatory to institutional and perhaps back home again or into a long term care setting; (3) communication of critical test results – that is communications in general within institutions concerning critical life saving and life preserving types of information; (4) reporting and disclosure to patients when something goes wrong. Twenty hospitals in Massachusetts are participating in a retrospective survey of recently discharged patients from those institutions, in terms of what their experiences were in the hospitals, what and how information was disclosed to them if something bad had happened to them during that hospitalization."

Ms. Ridley spoke of the newly created Betsy Lehman Center. The Center has a Patient Safety Board composed of the Executive Office of Human Services, the Office of Consumer Affairs, and the Attorney General. The Lehman Center will serve as a clearinghouse for the development, evaluation, and dissemination of patient safety education training and best practices. The Lehman Center will coordinate state programs for patient safety.

Discussion followed by the Council. During discussion, Council Member Dr. Williams added, "I am a practicing surgeon so I see these problems in hospitals. I would say that over the last two years, I think that there has been an improvement in the institutions, as far as investigating all complaints; that now they routinely do a root cause analysis whenever there is a problem; and I think by changing the culture of blame, that at least when I am working with my surgeons, I can then try to figure out system changes that will assist them rather than being afraid of people just pointing fingers at them. If you continue with that, I think that this will be successful. We will save a lot of lives in Massachusetts."

Chair Ferguson added in part, "…We will be announcing shortly a series of efforts that are designed to use some of the new technology and the new communication capacity that we have to really challenge some longtime practices that could clearly be updated and lead to better outcomes."

No Vote/Information Only

NOTE: For the record: Chair Ferguson left the meeting for 10 minutes at the start of Ms. Sheetz's presentation on item #3 below and returned at the end of Louise Goyette's presentation on item 4b. During her absence Council Member Sherman chaired the meeting.

REGULATION: Limited Staff Discussion

REQUEST FOR FINAL APPROVAL OF PROPOSED AMENDMENTS TO REGULATIONS GOVERNING ADMINISTRATION OF PRESCRIPTION MEDICATIONS IN PUBLIC AND PRIVATE SCHOOLS – 105 CMR 210.000:

Ms. Anne H. Sheetz, Director of School Health Services, accompanied by Attorney Howard Saxner, Deputy General Counsel, presented the final amendments to 105 CMR 210.000, to the Council. Staff has amended the regulations for the following reasons:

- Increased numbers of children with life-threatening allergies are attending before and after school programs.

- The current regulations permitting unlicensed personnel to administer epinephrine (provided the school is registered with the Department for this purpose) are limited in scope to the regular day.

- Epinephrine is the drug of choice to be used in the emergency management of a child experiencing a potentially life-threatening allergic reaction. Fatalities may occur when epineprhine is withheld or delayed.

- In the absence of regulations governing before and after school programs, epinephrine may not be legally administered by non-licensed school personnel in such programs.

- The proposed regulations provide school officials, parents, health professionals, and educational personnel alike with the guidance necessary to guarantee safe and proper administration of epinephrine during before and after school programs.

- The proposed regulations will provide consistency with the recommendations of the Department of Education for before and after school programs.

- **KEY FEATURES OF THE PROPOSED AMENDMENTS:**

The proposed amendments set uniform standards for safe and proper administration of epinephrine by unlicensed personnel in before and after school programs, provided the school or school district is registered with the Department for this purpose. The regulations require that the school committee or chief administrative officer in a non-public school approve a policy for the administration of epinephrine in before and after school programs. If the policy so provides, epinephrine may be administered to a student from another school or school district, provided that certain requirements are met. In addition, the regulations:

- Establish a process for determining which before and after school programs may be covered under the regulations;

- Define the storage requirements for epinephrine, in such a manner as to allow rapid access by authorized persons;

- Clarify that the administration of parenteral medications may not be delegated to unlicensed personnel with the exception of epinephrine as described in 105 CMR 210.100; and

- Require unlicensed staff to be properly trained and supervised by a school nurse.

The Department received written and/or oral testimony from five sources: the Board of Registration in Nursing, the Asthma and Allergy Foundation of America/New England Chapter, school nurses from one school district, one parent of a child with severe allergies and Representative Mary Jane Simmons. The comments were generally favorable, although there were some suggestions for revision or clarification. The following represents a summary of the Department's response to the major concerns:

1. **Concern about providing epi-pen administration to students from other schools**. School nurses from one school district raised concerns about taking responsibility for administration of epinephrine to students not attending their schools**.** as well as the time that may be needed for arranging coverage and training school personnel. The Department has responded by clarifying the requirements for students from other schools. The revised regulations (a) give the school nurse authority to determine whether epinephrine will be administered in these programs, (b) strengthen the language about providing adequate advance notice to the school

nurse, and (c) clarify the circumstances under which students from other schools might be given epinephrine.

2. **Concern about the language specifying that the school committee or chief administrative officer provide an assurance that sufficient school nurses are available to provide proper oversight of the program.** On review, Department staff concluded that it would be difficult to establish meaningful standards for such oversight. Accordingly, the language has been deleted. On the other hand, Department staff believes that it is important for schools and school districts, as registrants under c.94C, to recognize their responsibility for complying with the regulations. Language has been added to the regulations to address this concern.

3. **Need to include the dosage in the child's medication order:** This was added to the regulations.

4. **Need for proper disposal of a used epinephrine device:** A requirement for procedures to dispose properly of a used injector was added.

After consideration, upon motion made and duly seconded it was voted unanimously (Chair Ferguson not present to vote) to approve the **Request for Final Approval of Proposed Amendments to Regulations Governing Administration of Prescription Medications in Public and Private Schools – 105 CMR 210.000;** that a copy be attached and made a part of this record as **Exhibit Number 14,767**; and that a copy be forwarded to the Secretary of the Commonwealth.

Proposed Regulations: No Vote

INFORMATIONAL BRIEFING ON PROPOSED AMENDMENT TO 105 CMR 430.000: MINIMUM SANITATION AND SAFETY STANDARDS FOR RECREATIONAL CAMPS FOR CHILDREN, STATE SANITARY CODE, CHAPTER IV:

Mr. Brad Prenney, Acting Director, Division of Community Sanitation, presented the proposed amendments to 105 CMR 430.000 to the Council. Mr. Prenney said in part, "… The regulations were most recently amended in June of 2003. At that time, the Department's final mark-up galley showing all revisions to be made in the regulations inadvertently failed to indicate that section 105 CMR 430.204(B) remained in the amended regulations. As a result, the Secretary of State's Regulation's Division revised the regulations deleting the existing 105 CMR 430.204(B), a section that requires camp operators to determine a camper's swimming ability at the first swim session. The Division of Community Sanitation (DCS) now seeks to redress this error by returning the swimming test provision to 105 CMR 430.000. The proposed amendment will re-incorporate the deleted section (formerly 105 CMR 430.204(B)) back into 105 CMR 430.000. As required by M.G.L.c.30A, the Division of Community Sanitation hopes to move forward with a public hearing on this matter and bring the amended regulations back to the Council.

NO VOTE/INFORMATION ONLY

INFORMATIONAL MEMORANDUM REGARDING AMENDMENTS TO 105 CMR 130.000: HOSPITAL LICENSURE, AND 105 CMR 170.000: EMERGENCY MEDICAL SERVICES SYSTEM, FOR TRAUMA SYSTEM IMPLEMENTATION:

Ms. Louise Goyette, Director, Office of Emergency Medical Services, noted in part, "…The changes in EMS regulations are surprisingly minimal. What we bring forth substantively really represents three years iterations of having a wide range of experts in trauma in Massachusetts at the table primarily in a committee that was established by the EMS 2000 legislation. What that committee built on was a plan that had been developed in a three-year federally-funded project that laid out some principles around what the trauma system in Massachusetts might look like. The State Trauma Committee revisited that plan and built on it from there. From there, we went to the Emergency Medical Care Advisory Board, commonly known as EMCAB, and had them approve, with great gusto, the State Trauma Plan. We gave the EMCAB an opportunity to comment on these proposed regulations and those comments have been incorporated as appropriate in both sets of the regulations. This is such a cornerstone, another benchmark because the whole EMS 2000 vision, and the whole national trend in developing the EMS systems really is a response to the fact that was commonly known all the way back to the Korean War, that many people die of major traumatic injury because they do not quickly get to the right kind of care. That is what we are laying the groundwork for in these two sets of regulations."

Ms. Goyette continued, "…These regulations would require that EMS services, now ambulance services and EFR services established in the previous sets of regulations, would be required to comply with Regional Point of Entry plans, and that the EMS services, again both ambulances services and EFR services, provide to the Department relevant pre-hospital data. That has not really been defined any further than that, but the good news is that, come the end of the year, we will have a national consensus document on a national pre-hospital data set that I think will probably be the foundation for this data collection. A lot of that work has been done nationally over the past several years, that many folks on my staff and myself have been involved in…we are very excited about taking this step forward, however, the weight of these regulatory changes will be on the hospital and Paul will speak to that."

Dr. Paul Dreyer, Director, Division of Health Care Quality addressed the Council next, "We have amended the hospital regulations to define designated trauma centers as hospitals that meet the standards of the American College of Surgeons for designation…No hospital may use the term Trauma Facility Center or similar terminology unless it provides a trauma service as a designated trauma center. There is a subtle distinction here because we are not requiring that every hospital be designated. There are hospitals that are called systems hospitals, which are those hospitals that choose not to be designated. They can still provide trauma services. They cannot hold themselves out as trauma center."

Staff further noted, "A hospital may be designated by the Department as a trauma center if it has been verified by the American College of Surgeons (ACS) as a Level 1, 2 or 3 adult trauma center, or a Level 1 or 2 pediatric trauma center; enters into transfer agreements and provides consultation with lower-level trauma centers or system hospitals; and provides to the Division of Health Care Finance and Policy (DHCFP) the designated trauma center data set to be jointly

established by the Department and DHCFP and promulgated by the Department. Over the two-year period from the date of promulgation, the proposed regulations phase in the trauma center designation requirements, to allow for hospitals progressing through the ACS verification process that are recognized in regional point-of-entry plans as trauma destinations, to also be designated as trauma centers."

Staff continued, "Under the proposed regulations, a hospital may choose not to seek trauma center designation, but if it is licensed to provide emergency services, it must then meet the requirements of a "system hospital." A system hospital would be required to enter into written agreements with trauma centers that address transfer of patients to those centers, and provide to DHCFP the system hospital data set to be jointly established by the Department and DHCFP and promulgated by the Department. A designated trauma center that plans to change its ACS verification status or become a system hospital would be required to notify the Department 90 days prior to the proposed effective date for such a change.

The proposed regulations require Regional EMS Councils to develop, submit to the Department for approval, and if approved, implement, point-of-entry plans. Within two years of the effective date of these regulations, the Regional EMS Councils will develop and implement Department-approved trauma point-of-entry plans, which at minimum must include the designated trauma centers. The proposed regulations would require ambulance services and their EMTs to deliver patients in accordance with Department-approved regional point-of-entry plans, and prohibit development of independent point-of-entry plans. The proposed regulations also introduce a requirement for ambulance services to submit to the Department data as requested by the Department, including but not limited to data pertaining to prehospital care and transport of trauma patients. The Department would establish such data submission requirements in administrative requirements, which would be subject to the same 60-day review and comment period for all ambulance services prior to adoption as currently in place for certain other ambulance licensure administrative requirements."

NO VOTE/INFORMATION ONLY

INFORMATIONAL BRIEFING ON AMENDMENTS TO STANDARDS FOR PRESCRIPTION INFORMATION AND SECURITY 105 CMR 721.000:

Mr. Grant Carrow, Director, Drug Control Program, was accompanied by Attorney Howard Saxner, Deputy General Counsel. Mr.Carrow said, "…The Department has an opportunity today to take steps to address the issue of medication errors in the community setting, as well as address issues of prescription fraud and abuse. Electronic transmission of prescriptions can help reduce medication errors, such as those caused by illegible writing. They can also reduce prescription fraud, such as reducing forgery. However, we have to take care in not allowing electronic systems to be so used so that they can produce additional opportunities for fraud and abuse, and error, such as through transmission errors, or forgery, such as through hacking into systems, as well as, we have a concern that there not be breeches of patient privacy. The regulations that we are proposing would address these issues by instituting standards for format

and security that would ensure the safe, reliable transmission of electronic prescriptions. The proposed standards would hopefully assure prescribers, pharmacists and patients that they can have the trust and confidence in the systems to adopt the electronic prescriptions; and, in addition, the regulations would allow for the automatic authentication and validation by pharmacists of prescriptions so that pharmacies can increase efficiencies, lower costs, and increase public health and safety in the Commonwealth."

Ms. Nancy Ridley, Assistant Commissioner, Bureau of Health Quality Management, added, "We see this as a phenomenal opportunity to increase patient safety. Electronic transfer and electronic transmission has the very, very strong potential, obviously it has some risks, as Grant mentioned, but it has been demonstrated to show that it has some very high potential for major improvements in patient safety. Medication errors are probably one of the most frequent problems and translation of handwriting and information is often at the root cause, no matter whether it is in a hospital, or it is in the ambulatory setting, and Massachusetts has been a leader, and actually this is one of the questions I was being asked out there, Massachusetts has been a leader in computerized physician order entry. It was developed by one of our institutions, and really, the computerized technology is something that we really look forward to."

Discussion followed, whereby Dr. Sterne inquired about the current practice of faxing prescriptions versus the proposed electronic transfer of prescriptions. Mr. Carrow clarified that the current system of fax or e-mailing will still be allowed under the proposed regulations. The proposed regulations allow an additional venue – electronic transfer of written prescriptions. "Faxes are unsecured transmission and additional validation steps must be taken by the pharmacist. We are trying to eliminate the extra steps," said Mr. Carrow. "Currently, the statute allows both written and oral prescriptions. Because it allows for oral prescriptions, it allows for unsecured means of transmission of prescriptions. We do hope and encourage industry and patients, and we believe market forces will push people to adopt these more secure methods, and to eliminate things such as oral prescriptions, which can add to medication errors."

Ms. Ridley noted that the fear about fax prescription fraud and abuse has not materialized however she said, "the faster we move towards secured electronic transmission that goes beyond fax and allows for these data stream bits to take the place of the paper-based faxing system, I think the better off we will be, but that is going to take some time."

Council Member Thayer inquired, "Why do prescriptions require the phrase, 'no substitutions' in order for a person to receive the name brand drug." Ms. Ridley replied, "…The legislature and the Department have tried to make it as difficult as possible to prescribe name brand drugs. It requires that a physician actually put a great degree of thought behind writing a brand name medically necessary prescription. We are very strong supporters of generic drugs by equivalency substitution of lower cost drugs." **NO VOTE/INFORMATION ONLY**

INFORMATIONAL BRIEFING ON AN AMENDMENT TO DETERMINATION OF NEED REGULATIONS 105 CMR 100.000 GOVERNING APPLICATIONS FILING DAY FOR CONVALESCENT, NURSING AND REST HOME RENOVATION AND REPLACEMENT PROJECTS:

Ms. Joyce James, addressed the Council, "The purpose of this memorandum is to inform the Council that the Department staff plans to hold a public hearing on a proposed amendment to the Determination of Need Regulations 105 CMR 100.302, Filing Days for Applications and Amendments. This amendment changes the filing day of Determination of Need (DoN) applications for alteration of, making of major repairs to, remodeling of, or replacement of convalescent, nursing and rest homes from the first business day of January, to any business day, following adoption by the Council and final promulgation of the proposed amendment."

Staff noted that since 1994, these applications have been reviewed under the delegated review process, i.e., approved administratively by the Commissioner of Public Health (unless adverse comments are filed or the Commissioner decided not to approve the project; then the application would be presented to the Public Health Council). Staff said further, "Since applications for delegated review are unique applications that may be filed on any business day, this proposed amendment will do the most possible under current law to "level the playing field" for nursing and rest home facilities seeking to replace and modernize their physical plants. Additionally, the proposed amendment would allow applicants sufficient time for more adequate planning and preparation of applications prior to filing." **No Vote/Information Only**

INFORMATIONAL BULLETIN ON ANNUAL ADJUSTMENTS TO DETERMINATION OF NEED EXPENDITURE MINIMUMS:

Ms. Joyce James, Director, Determination of Need Program, presented the request for approval of the annual adjustments to the DoN expenditure minimums as required under M.G.L.c.111,s.25B ½. Ms. James indicated, "These indices have been chosen by the Determination of Need Program as an authoritative resource due to their extensive use within the health care industry to determine inflation rates for a number of health care expenditures. While each of the indices has various regional and market sector subtleties and shadings, it is important for ease of administration to use a single inflation factor for capital costs and a single factor for operating costs. Thus, Marshall & Swift's statewide figures are used for the capital cost inflation and the average of DRI/McGraw-Hill hospital and nursing home figures is used as the basis for recalculating inflated operating costs. The precise mechanisms for these calculations are set forth in Exhibit A. The newly calculated expenditure minimums are set forth in Exhibit B."

After consideration, upon motion made and duly seconded, it was voted unanimously [Council Member Sherman not present to vote] to approve the request for adoption of the **Informational Bulletin of Annual Adjustments to the Determination of Need Program,** memo dated October 28, 2003. These figures are effective October 1, 2003. The approved Bulletin follows:

ANNUAL ADJUSTMENTS TO DETERMINATION OF NEED EXPENDITURE MINIMUMS:

The Determination of Need Regulations 105 CMR 100.020 require the Department of Public Health to adjust expenditure minimums (for inflation).

Capital Cost Indices (Marshall & Swift):

	October 2002	October 2003
REGION- EASTERN	1931.3	1989.7
Massachusetts	1.11	1.10

$$\frac{1989.7}{1931.3} \times \frac{1.10}{1.11} = 1.0210$$

Operating Costs (DRI/McGraw-Hill):

	4th Quarter	4th Quarter 2003
Skilled Nursing	1.217	1.254
Hospital	1.208	1.253

$$\frac{(1.254}{(1.217} + \frac{1.253)/2}{1.208)} = 1.0338$$

Capital Expenditure

Project Type	October 1, 2002	Filing Year Beginning October 1, 2003
Equipment for non-acute care facilities and clinics	$556,405	$568,066
Total capital expenditure including equipment for non-acute care facilities and clinics	$1,112,812	$1,136,133
Capital expenditure, excluding major movable equipment, for acute care facilities and comprehensive cancer centers	$10,432,608	$10,651,247

Operating Costs:

Project Type	October 1, 2002	Filing Year Beginning October 1, 2003
Nursing, Rest Homes and Clinics	$582,529	$602,234

COMPLIANCE MEMORANDUM:

PREVIOUSLY APPROVED PROJECT NO. 4-3966 OF METROWEST MEDICAL CENTER – PROGRESS REPORT ON COMPLIANCE WITH CONDITIONS OF APPROVAL FOR TRANSFER OF OWNERSHIP:

Ms. Joan Gorga, Analyst, Determination of Need Program, presented the MetroWest Medical Center Progress Report to the Council. She said, "Last September, staff presented to you the fourth progress report submitted by Metrowest Medical Center and the Metrowest Community Health Care Coalition regarding the ten conditions of Project No. 4-3966, which was approved by the Council in February 1999. At that time, the Council found that, while MetroWest had shown progress in complying with the conditions by working with the Coalition, additional time and attention were necessary to achieve full compliance with the conditions.

Staff is pleased to note that there has been progress in the past year, and that the Coalition reports they have had cordial and productive communications with MetroWest around the ten conditions. The transportation continues to be a difficult problem to solve, and the Coalition has indicated that, in the absence of a permanent solution, it finds taxi vouchers used by MetroWest an acceptable interim step. The Coalition reports that it has emphasized the need for increased awareness of the voucher system among hospital staff and the community."

Ms. Gorga continued, "Both MetroWest and the Coalition reported this year that the issue of continuity of interpreter services, which was raised in last year's progress report, was addressed and resolved during the year. Staff has found that MetroWest is now in full compliance with all of the conditions of approval of the transfer of ownership and original licensure. In order to assure continued compliance with the conditions, the hospital and the coalition have developed, signed and submitted to the Department a Memorandum of Understanding, which outlines procedures to ensure a continuation of the progress demonstrated over the past several years. As noted in the staff summary, the Coalition and MetroWest Medical Center agree to meet at least three times per year to review, discuss and collaborate on each of the ten conditions. In the Memorandum of Understanding, both the Medical Center and the Coalition agree that each reserves the right to contact Public Health Council in the event that either party is aggrieved by the actions of the other with regard to the ten conditions. In addition, the local advisory boards of the Medical Center, which are composed of medical staff, community groups and the public have voted to review the ten conditions at least once every six months. Based on these assurances, staff is pleased to recommend that no further progress reports be required for MetroWest on the fully implemented conditions. Staff will, of course, be available to assist either party in contacting the Public Health Council if necessary."

A brief discussion followed, whereby Council Member Slemenda asked, "if the memo of understanding precluded in how long?" Ms. Gorga replied, "It is good in perpetuity."

After consideration, upon motion made and duly seconded, it was voted: unanimously [Council Member Sherman not present to vote] to approve staff recommendation that **MetroWest Medical Center will no longer be required to submit annual progress reports on the compliance with conditions of approval relating to Project 4-3966;** and that a copy of Staff's report and attachments be attached and made a part of this record as **Exhibit Number 14,768**

Staff's recommendation was based on the following findings:

1. The Department found that MetroWest Medical Center worked collaboratively with the MetroWest Community Healthcare Coalition to successfully achieve full compliance with all conditions of approval relating to statutory free care, voluntary free care, cultural competence, community benefits, continuity of care, mental health and substance abuse, employee relations, transportation, governance, and enforceability.

2. The Department found that MetroWest Medical Center and the MetroWest Community HealthCare Coalition have agreed to meet at least three times per year to review, discuss and collaborate on progress made on each of the ten conditions outlined in the Notice of Determination of Need issued March 5, 1999. Each party will reserve the right to contact the Public Health Council in the event that either party is aggrieved by the actions of the other relative to the ten conditions. This arrangement has been formalized in a Memorandum of Understanding (MoU) signed by the Chairman of the Coalition and the Chief Executive Office of MetroWest …. In addition, MetroWest Medical Center indicated that the ten conditions will be reviewed by the Local Advisory Boards no less than once every six months.

Note: Attorney Donna Levin, General Counsel, Department of Public Health, stepped down, on the basis of 268A. Attorney Susan Stein, Deputy General Counsel, Acted as Counsel to the Council for the following two docket items 6b and 6c:

PREVIOUSLY APPROVED PROJECT NO. 1-4677 OF WESTERN MASSACHUSETTS MAGNETIC RESONANCE SERVICES, INC. – REQUEST FOR A TRANSFER OF SITE OF A MRI SERVICE:

Dr. Paul Dreyer, Director, Division of Health Care Quality, presented the request for transfer of site of project No. 1-4677 of Western Massachusetts Magnetic Resonance Services, Inc. to the Council. He explained a prior situation regarding a radiation therapy transfer of site, which was based on the Determination of Need Regulations in place at that time. In August of 2001, new regulations were promulgated that clarified the Transfer of Site Criteria under DoN Regulation 105 CMR 100.720 (I) (1) and (2). A request for a transfer of site under 105 CMR 100.720 shall be approved if the Department determines that no substantial change in service or substantial capital expenditure will result and one of the following applies: The proposed transfer will not substantially change the population served by the facility, defined as the population residing in the cities and towns whose patients when ranked ordinally contribute cumulatively 75% of the facility's total discharges; provided that the transfer of site request shall not be approved if the proposed site of the transfer is a city or town that ranks higher on the 75% discharge list of another facility that provides the same services than it does on the 75% list of the facility proposing the transfer, unless there has been demonstration that the proposed transfer will not result in the duplication of services; or the proposed transfer will significantly increase access to the service for the population residing in cities and towns of the new site, and will not result in a corresponding decrease in access to the service at the original site.

Dr. Dreyer spoke about the criteria above and said in part, "…The question is, what do we mean by increased access? What we mean, and what we meant when we wrote the regulation is, it will meet an unmet need in the new service area. What this test says is you can leave your service area so long as the area you are leaving behind is not going to be short with respect to the service, and the area that you are going to will benefit from increased access to the service, which means that unmet need…increased access does not mean contribute to an oversupply....This is perhaps easiest to understand if you think about transfers of the site of nursing homes. If you are moving a nursing home from Town A to Town B, outside the service area, maybe sixty miles away, if Town A is oversupplied with nursing homes, you are fine, and you can move to Town B if Town B doesn't have a sufficient supply of nursing homes. If Town B already has nursing homes occupancy rates of 85%, and it is clear that there is an oversupply, then you can't move to Town B because you wouldn't be increasing access. You would be increasing supply, but you wouldn't be increasing access. That's the standard that we use in analyzing these cases, and I think Joyce is now going to go through the Western Mass. Application."

Ms. Joyce James, Director, Determination of Need Program, stated, "…The issues under consideration regarding this proposed transfer of site are (1) does the applicant meet the 75% rule? (2)Has it a greater marketshare in Hadley, the proposed site than another facility in the area who is also providing MRI service. And that facility is Cooley Dickinson Hospital. (3) If Cooley Dickinson has a greater marketshare in Hadley, we can go ahead and approve this project, provided it does not result in a duplication of service. The final issue is, will this proposed transfer of site significantly increase access at the proposed new site without a corresponding decrease in access at the former site….The other issue, duplication of service, we find that even if Hadley had run higher in Cooley Dickinson's discharge data, we could not approve this transfer of site because it will duplicate service, and it will duplicate service because the service area that Western Mass. is proposing to serve is the service area of Cooley Dickinson Hospital, which already has an MRI unit that is able to perform the MRI service projects, MRI scans projected by Western Mass. The final issue is – does this transfer of site – will it significantly increase access at the proposed new site? No, it will not. Why? Cooley Dickinson, whose service area is in the proposed new site, is operating a unit that is underutilized. That tells us that there is not sufficient patient volume in the proposed service area to support two units. Based on these findings, we are recommending denial of the transfer of site…."

Attorney David Harlow of Posternak, Blankstein and Lund, representing the applicant, testified before the Council. Attorney Harlow said, "The application that is before you today is a request for a transfer of site of the previously approved and previously licensed project, and the staff's presentation, I believe applies a rule different than what is applicable in this circumstance. In fact, the staff analysis that is before you supports approval of the request in all respects but one. In analyzing the question of whether the proposed transfer of site would significantly increase access in the destination community, Hadley, the staff found that it would not, and was therefore recommending denial. What the staff memo shows is that there is no need for additional MRI in the system. However, while we do not disagree with that conclusion, it is the answer to the wrong question. The applicant today is not applying for a new Determination of Need. This Determination of Need has been held for over fifteen years, and the applicant before you today is

one of the pioneers of MRI service in Massachusetts. The question is simply whether relocation of the already licensed MRI unit will significantly increase access to MRI for residents of the service area centered in Hadley."

Attorney Harlow continued, "Obviously, admittedly, we are talking about overlapping services area. That does not detract from the conclusion that the relocation of the MRI unit would be increasing access in Hadley and in surrounding services area….Why is Western Mass. requesting a Transfer of Site from its location at Cooley Dickinson to a new location in Hadley? The simple reason is that the Department staff issued a 105 CMR 100.308 exemption, in the absence of determining need under the long-established rules for MRI, the Department staff has made the policy decision to grant 308s for MRI units to acute care hospitals that do not already have their own DoN approval for MRI, even as in this situation, where MRI is already being provided in the service area by another provider that has received a DoN, and has been licensed and operating for many years. The reason for this is to allow acute care hospitals to develop services in areas where they previously had not had services, and MRI, for one, is an extremely profitable line of service for hospitals. We are not opposed to the survival of hospitals, but if DPH is going to effectively revoke a previously issued DoN granted to Western Mass., DPH should at the same time be willing to grant Western Mass. the ability to continue to provide the long-approved and licensed service in a location of its choosing so that it can continue to operate the business that is has built from scratch over the past 15 years."

Attorney Harlow said, "The staff memorandum presents a transfer of site analysis as a variation on the game of musical chairs, and that is not what it is supposed to be. A DoN once granted is revocable only in very extreme circumstances, and those circumstances are not present here. Under the rules of the Department, there is no need for more MRI at Cooley Dickinson Hospital, yet the staff issued an exemption for DoN to allow Cooley Dickinson to obtain its own MRI unit."

Brief discussion followed, whereby, Atty. Harlow stated that the patients in question belonged to Western Massachusetts Magnetic Resonance Services, Inc., that is a licensed clinic in the Commonwealth; the patients received their scans at Western Mass. in their mobile unit six days a week; and that the marketshare data also belongs to Western Mass.

In closing, Attorney Harlow said, "We are here today to ask you to and urge you to use your discretion to reject the staff recommendation….I would further note that if you were unwilling today to reject the staff recommendation and approve the application…that you instruct staff to analyze the issue that should be analyzed; which is whether, by moving to Hadley, there would be increased access to services in Hadley by people in the proposed service area, the proposed new site for this resource. The answer to that question is yes. It is a common sense analysis. If you move the resource into a town that has not had that resource before, you will certainly increase access to that resource. Access is not measured really by the question of whether there is need for an additional MRI unit. That's the wrong question to be asking here. The real issue is, can someone in Hadley or the surrounding towns, within the service area that would be served by this resource in Hadley, do they have better access to MRI if there is a MRI in Hadley, and the answer to that is yes."

Dr. Michael Tucchio, Senior Vice President, Alliance Imaging, addressed the Council. He stated, "My issue here is fairness. The reality is - we have for years provided service on the campus of Cooley Dickinson Hospital. We have built the business. We feel that it was our business. We did negotiate in good faith with the hospital to try to continue the service there. They chose not to because it was relatively easy for them to go ahead and get a 308 provider in service. Cooley Dickinson is a good hospital. It has good people in it. We want to see it survive and flourish, but the reality is, you are basically taking us out of business. For years, we have helped build the business. We drove the business. We provided an excellent service in that community and you have basically revoked our license. I have 340 people that work for Alliance Imaging. People are losing their jobs. If this continues, they will continue to lose their jobs. It is not fair. We have the DoN. We were providing service there. We understand the hospital's right and accept the hospital's right to have their own service. We commend that right, but to put us out of business when we have also a right to provide service is unfair. It is unreasonable….We are not asking for anything other than to continue to provide service in the area, and service that we have built, and continue to work arm-in-arm with the hospital, and with the health care providers in that area to continue providing the service in an area that really does have an access issue in our opinion."

Council Member Sherman inquired about the 340 people to be laid off at the Cooley Dickinson site. It was clarified that 16 people worked at that site, some were laid off and some relocated to other Alliance Imaging sites and that was about a year ago. Dr. Tucchio stated that he was worried about the trend. Attorney Harlow, added, "To put this in the broader context, in terms of the effect on Alliance, the 308 is granted to hospitals in this situation and in four other circumstances that have resulted in effective revocation of DoNs issued to Alliance entities. Whatever, numbers we are talking about in terms of staff at Cooley Dickinson may be multiplied by five. That is the total number of MRI units that have been effectively taken out of service by the Department's issuing of 308s to hospitals that were formerly host hospitals." In addition, Atty. Harlow noted, "The hospitals receive 50 to 100% more per MRI scan than a free-standing clinic for reimbursement. He said, "In terms of the DoN mission of cost containment, this policy of the Department has had the exact opposite effect of what you would like to be doing, and to date has resulted in what I would estimate something on the order of 14 million dollars in excess reimbursement payments to hospital MRI providers versus what would have been paid to clinic MRI providers operated by Alliance Imaging."

Council Member Sterne made some comments, "One is that you have no knowledge whatsoever of what demand for MRI services would have been like if there had been two facilities instead of one. One can't make an adequate estimate about the cost of MRI and/or the medical appropriateness without factoring a lot more in than simply the reimbursement rate to a hospital-based as opposed to an independent-based entity. Granted, what you say may very well be true, but it is not proven, and the phenomena of the sheer existence of facilities generating their own demand ipso facto is one that, in part, the Determination of Need process was designed to at least look at, if not control. That's number one. Number two, the access question – If I have a candy store next to my home, I am going to buy more candy than if it was a six block walk, but that in no way, shape or form indicates that I think having it six blocks away is a major access issue. The notion of having some facilities at some distance - that takes some cost in terms of effort and

transportation is not in and of itself an inherently abhorrent idea because it acts somewhat as a deflection against fickle and arbitrary use."

Dr. Sterne continued, "The question isn't whether or not access next door would generate more people from Hadley getting MRIs. You may very well be right. The question is still whether or not having the concept of having a high tech, high expense piece of machinery in a given regional area at full capacity before having more of them is an appropriate or inappropriate concept in today's economic world, and I will put aside the answer to that because different people feel differently about that….The only issue on which I think your case makes sense to me is the issue that goes back to the original purpose of the Determination of Need process, which was in a sense to have some failed, historically speaking, attempt to control medical costs by controlling arbitrary expenditures of high amount of capital, aside from the technologic issues involved, independent of the technologic or medical issues that would not necessarily have taken the forefront in a strictly market-driven system. And there, I think you are legitimate in asking the question of whether hospitals in and of, and by themselves, should have had rights with regard to expansion in the setting of an existing facility, that they receive through no fault of your own, and certainly in spite of your effort in establishing an effective product on site. My last request would be for staff to come back and answer that for me, at least in a historical context because I recognize that by the letter of the law, which I believe that by the letter of law that what staff is describing is the rule, and if in fact that is the regulation, I will be inclined to vote against you as an entity. But I would like, in the issues of fairness because I believe in that, too, to understand why that rule exists, or existed, or was put into place, and resulted in the displacement of entities like your own, or potential displacement of entities like your own."

Commissioner Ferguson, Chair, added, "…The issue here is the original 308 process – that is what you are contesting. It comes up in this context, but that is really the issue, and I think that is worth conversation, but it does not fall within the parameters of what we are discussing today." Atty. Harlow replied, "…I respectfully disagree that the regulatory test here is being misapplied in the staff memorandum, that there was a previously approved DoN for Western Mass. Magnetic Resonance Services that has been displaced and forced to come before you in this posture because of the 308 issued to the hospital, and having come here in that posture, what we are simply looking for is fair treatment under the rules, and to be recognized as an existing provider rather than as a new provider, which is how we are being looked at in the way the questions are being framed by the staff." Drs. Howard Raymond, Chief of Radiology, Holyoke Hospital and Noble Hospital in Western Massachusetts noted that there was an access problem in western Massachusetts and that is why he supports the Western Mass. project, especially in light of the Calvin Coolidge Bridge being repaired at this time. The Council responded that the bridge would be repaired some day and that would alleviate the traffic problem.

Attorney Steven Weiner, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., representing Cooley Dickinson Hospital testified and said in part, "…We support the staff recommendation…with regard to the history of this situation, the characterization of this actually being a matter of sort of broader Department of Public Health policy in the MRI area is quite correct; and in some respects, Cooley Dickinson should not be disadvantaged in this particular context by virtue of a more general policy, but there is a piece of history I think is important.

The Western Mass. Model was actually instituted in some of the early days of the dissemination of MRI services. As it was moving out of the teaching hospital setting, and into the community hospital setting, the Department was looking at various ways of controlling, to a certain extent, that dissemination while, at the same time, allowing it to be taking place in a kind of, if you will, a model environment. The Western Mass.model involved the issuance of a DoN not to Western Mass. by itself, but to Western Mass. and the individual hospitals at which the services would be provided so that Cooley Dickinson and Western Mass. shared the DoN, as by the way do three other hospitals in the original approval. The concept behind that model was, because the principal purpose of this was in fact to provide access to the hospital's traditional service area, and the hospital's traditional population, but to allow a vendor relationship with a company like Western Mass. or Alliance, to allow the dissemination to be somewhat more controlled, done on a partial basis a few days a week rather than seven days a week, a more economic investment in the high cost technology, so that, at the time, no individual hospital had to go out and invest in a full MRI unit for seven days a week, 24 hours a day. It was a model that worked in the early stages."

Atty Weiner continued, "Clearly what has happened, what you are seeing in fact by the comments made by the applicant today is over the years, that model has changed and the Department, frankly, has been in the forefront of assisting that because MRI has become an accepted technology, the demand for it has increased, the applications for it have increased, the costs have decreased, the unit costs have certainly come down, and the use of the 308 process, that has been referenced in previous comments, has really been the Department's way of saying to hospitals, if you wish to have your own service and control your own service, you may do so. For example, in Cooley Dickinson's place, under contractual arrangements with the vendor, Western Mass., it was permitted to terminate that arrangement, but it had to therefore deal with the question of how to provide MRI services to its own traditional population that had been receiving it through the Western Mass. model, and that is why the 308 was granted, and that is why we are now in a situation where, for over a year now, Western Mass. has not been providing services at the site. Of those 16 employees, some in fact were, I believe, employed by the hospital, the ones that the hospital felt were the most able to sort of step in and continue the services…the hospital has been able to provide a more effective service, and a much better service, overall, for the citizens of the communities than was the case before."

In conclusion, Attorney Weiner said in summary, "The history is very important here, but the concept, that this was a franchise granted to Western Mass., and to be able to move it as they wished too , wherever they felt like taking it, in various parts of the state, is not accurate. It was an approval granted to the hospital and its vendor, to allow for a dissemination of the service at a point in time when one was not sure that full time services would be appropriate for a lot of those community hospitals." Discussion followed, In which it was noted that the applicant is in the process of filing for a DoN, in the data gathering stage, in contact with DoN staff and plans to file, the first week of December.

Mr. Craig Melin, President, Cooley Dickinson Hospital, addressed the Council. He noted (1) that building the permanent facility was the right thing to do for their patients because the truck was claustrophic for patients; and (2) economically it was the right thing to do for the hospital

(absence of middle man); and (3) that their original DoN approved one day in Northampton; not the six days that Western Mass. was actually providing the care for; (4) approval of Western Mass. would add unneeded capacity without improving access and contribute to deterioration of quality of care; (5) that the patients belong to Cooley Dickinson and not Western Mass. and that the population is the hospital's;(6) that the hospital has unused capacity (one in three slots on average every day are vacant. Cooley Dickinson runs the MRI service five days a week from 6:00 a.m. until 6:30 p.m.(providing 6800 scan slots). The hospital could expand to open on Saturday or Sunday evenings (adding another 1500 scan slots) but the demand is not there. Emergency patients are seen right away or the next day if not critical.

Mr. Melin, further stated (1) that Western Mass. inflated the national numbers on how many people would actually need MRIs. Mr. Merlin said, "What is the impact on the community? Let's assume for a moment that Western Mass. does bring in 2100, which is their estimate, for the first year. I think I would be charitable if I didn't say that at least 2000 of those patients would have been coming from Cooley Dickinson because they are planted right where all our patients are. Just to put the economics on the table, not off the table, 2000 patients at $1,000 dollars a patient, two million dollars – that's the revenue. The question in front of you, and it comes from the principles and guidelines you have – is do you need another million dollar facility and another half million dollars in expenses to pay for the 16 additional people to provide access in our community?..."

Dr. Paul Dreyer, Director, Division of Health Care Quality, addressed the Council, "…A couple of points, We spend some time talking about what access meant or didn't mean. I think the applicant's representative agreed that there was no need for additional service; and, to us, that is what we meant when we wrote the regulation with respect to access. If it didn't meet the need, then it didn't really mean anything. The point was, you don't want a facility moving to an area where there is already sufficient service; meaning we don't want a facility to move to an area where there is no need for it. That's what we meant by access when we wrote the regulation. Historically, I think it is the case that these DoN's were granted to both the hospitals in this area, and to Western Mass., and I think the conditions of the DoN were probably specific with respect to the conditions under which each could operate. Western Mass. was obligated, I think, to operate at the six hospitals, each one day a week, and it was obligated to file with the Department any change to that schedule. I think the hospitals were obligated, probably, to get their service through that modality. By giving the 308, we essentially allow the hospitals to change the arrangements under which they receive the service. I think we would agree with Atty. Weiner's characterization of the reasons for which we did that. At the time, the early 1980s, when this arrangement was made, it was one of several arrangements by which hospitals got MRIs and it wasn't clear that the best arrangements was going to be, and how successful this technology was going to be…When it became clear that this was a technology similar to CAT scan, or an x-ray machine that is part and parcel of a hospital's operation, it made abundant sense to allow hospitals to access the technology on its own. Now, with respect to Western Mass., it has a licensed clinic in Chicopee. I think there is nothing that would prevent it, under the current regulations, without a transfer of site, from operating at that licensed clinic. It is asking to move from its current licensed place based elsewhere, and so that is a transfer of site, which needs to be evaluated under these current regulations."

Ms. Joyce James, Director, Determination of Need Program, added, "I would add that the 308s were issued to hospitals as the technology advanced and MRI became a frontline diagnostic tool. We thought it would be reasonable to have such services available in a hospital. And further, because of the advancement in technology, the MRI units that were being manufactured at higher throughput as opposed to the older mobile units, which were limited in their capacity and could not support the hospitals. In other words, when we issued 308s, the hospitals' requesting them chief reason for the request was that the mobile service available to them was not adequate to cover the number of scans needed. A lot of the hospitals have moved from mobile service of two days to their own units where they had more flexibility and could provide more convenient hours for their patients."

Attorney Carl Rosenfield, Deputy General Counsel, Department of Public Health, stated that he was involved in the initial change of policy in regards to the 308 exemptions. He said that the initial characterization that the Department's willingness to grant 308s was a precipitating factor in the alteration in these relationships with the local vendor was not the case. He noted that the hospitals made the decision to acquire their own MRIs and that they could do so by paying someone else for the franchise, someone with a physician exemption, which would add a significant amount to the cost without any corresponding value. He further noted that the utilization of MRIs as a primary diagnostic tool led to the need for the hospitals to have this service on a long term basis.

Discussion followed by the Council. Ms. Pompeo, Council Member, asked staff is there had been a public process on the 308 policy change. Dr.Dreyer replied that no public process is required for exemptions. He did note that several years ago, there was a public process around deregulation of MRIs entirely. He said, "It was the consensus of most of the players, both hospitals and private service providers to continue the current regulatory structure. The argument that hospitals made, even though perhaps from a market point of view, deregulation theoretically made sense in the current fiscal environment, where hospitals are at some disadvantage being payers, MRI was a positive source of revenue and it would be a disadvantage for deregulation to occur."

Discussion continued. Ms. Pompeo questioned further, "Would a transfer of site to another location, bring up these same issues?" Dr. Dreyer replied, "If there was a need for the service, the analysis would be different." Commissioner Ferguson added, "Would it be fair to say then that the policy decision was basically made by the Commonwealth a number of years ago so that the transitioning of these services back into or in the hospital for the first time is a way of helping to maintain hospital capacity and revenue? As opposed to allowing freestanding entities, and that was in essence, putting hospitals in a favorable position, was the policy of the commonwealth." Dr. Dreyer replied, "Yes, I think the result of the policy was in fact to put hospitals in a favorable position…However, with respect to the 308s, some 308s have been granted to the non-hospital providers to provide service at their licensed sites, if they can pass the transfer of site test".

Council Member Dr. Sterne made a motion to accept staff's recommendation of denial. He noted in part, "…What I question is the competing motives and objectives of the need process, and in fact, there are competition in objectives, the goal of controlling costs – costs for high tech items conflicts with other goals to support a failing private hospital system or the goals of the free market economy and it is not clear to me what the rationale of the system in 2003 is or should be."

After consideration, upon motion made and duly seconded, it was voted: (Chair Ferguson, Mr. George Jr., Ms. Slemenda; Dr. Sterne, Mr. Thayer, Jr., Dr. Williams in favor; Ms. Pompeo and Mr. Sherman abstaining and Ms. Cudmore absent) to **deny** the **Request by Previously Approved Project No. 1-4677 of Western Massachusetts Magnetic Resonance Services, Inc.** for transfer of site, based on staff findings. A copy of staff memorandum dated October 28, 2003 is attached and made a part of this record as **Exhibit Number 14,769**. Staff's recommendation was based on Western Mass.' failure to satisfy 105 CMR 100.720(1)(1) that the transfer of site will not change the population served. Staff also finds that the proposed transfer of site fails to satisfy 105 CMR100.720(1)(2) because it will not significantly increase access at the proposed new site. The transfer of site will not result in a corresponding decrease in access at the original site, where Cooley Dickinson Hospital currently operates an underutilized fixed-site MRI unit.

GREATER BOSTON MAGNETIC RESONANCE IMAGING LIMITED PARTNERSHIP REQUEST FOR A TRANSFER OF SITE OF A PHYSICIAN-EXEMPT, FIXED MOBILE MRI UNIT FROM BROCKTON, MA TO A FIXED-SITE MRI UNIT IN NORTON, MA:

Ms. Joyce James, Director, Determination of Need Program, presented the request for transfer of site by Greater Boston Magnetic Resonance Imaging Limited Partnership. Ms. James said, "As, Paul said, this analysis is analogous to Western Mass. so I will be brief. The consideration for this replacement Transfer of Site is whether or not it will significantly increase access at the proposed new site. Comments opposing the transfer of site were submitted by Southeastern Massachusetts MRI, which provides services in all these areas. These comments are included in staff's analysis. These findings, as briefly summarized, are that the Transfer of Site will not significantly increase access at these sites. And the reason for this is because Greater Boston MRI projected service level, which in itself is quite small, is based on the population within a twelve mile radius of Norton. We find that there are already two MRI units in that area which currently provide service to the population within that twelve mile radius, and have the capacity to perform the service level or number of scans that Greater Boston is projecting. Based on these findings, we are recommending denial of the project."
Attorney David Harlow of Posternak, Blankstein and Lund, representing the applicant, noted, "…Given the similarities of issues between the Western Mass. application and the Greater Boston application, we request that for the purpose of the Council's record, the consideration of Western Mass, in terms of the context, be part of this record also. I don't want to repeat myself. To add to what I have said before [see Western Mass. Application above] I would like to focus on one of the linguistic issues which we are struggling with, which is the issue of need and the issue of access. The Department in general, and we in this area use need to mean a number of things, and Greater Boston owns a license for MRI. In this circumstance, pursuant to an exemption from the Determination of Need, like Western Mass. has a license pursuant to meet DoN, that there was need for additional MRI services to serve the population earlier on. Those

determinations were made by the department. The regulation that is at issue today is a regulation that speaks about access. I understand Dr. Dreyer has said that access means need. Well, with all due respect, it doesn't. If the Department meant need, it could have said need in the transfer of site regulation. The regulation does not say need. It has not defined access, and we are forced, I think, to revert to more or less a dictionary definition of access in considering whether a proposed transfer of site would indeed increase access to a resource. If access means something like becoming more readily available to patients, then both the Western Mass. application and the Greater Boston application should have gotten approved. It really means something along the lines of freedom or ability to reach or get to. That is what access means. I am not talking about need. There was a Determination of Need made early on by the Department. We are not asking that issue be revisited. What we are asking is that the applicant today be treated fairly. We put on the record today a rhetorical question - is there a need for another facility at this location? And the answer to that is no. I would agree that the answer to that is no. But if the question is, do we need another facility, which is the other facility? The other facility is the one that is followed on the development of a facility by Alliance Imaging. Alliance Imaging was licensed there first, and if the Department is looking at whether there is need for another facility, then it should have analyzed that question in the context of the 308 exemptions granted to the hospitals in this circumstance. The regulation does not equate need with access, and I don't think it is appropriate to do that. Having approved, having found need effectively on the 308 exemption process for another facility that has resulted in the termination of the ability of Greater Boston to provide MRI services in its previous, the question needs to be, I believe, you believe, what can the Department do in this circumstances in order to avoid an effective revocation of the Determination of Need that has been issued by the Department. The hospitals will and have argued and the staff has presented that the volume demands of hospitals cannot be met by mobile or fixed mobile units that have been historically provided by Alliance Imaging. In the case of the Western Mass. application that we just heard, in fact, the hospital, as the staff has found, has thirty percent of the utilized capacity. The 308 process, as described by staff, is a discretionary exemption from the DoN process, discretionary with the Department's staff. Granted the discretion however of the Department must be exercised reasonably in order to remain legal, to remain within the framework of a broader Determination of Need statute/regulation…"

Dr. Eyal Morag, Western Massachusetts MRI, stated in part, "I have one very interesting point and that is that the President of Cooley Dickinson Hospital told you that the average cost for an MRI is one thousand dollars. If you look at the record, the patients are Western Mass. patients. We have all of the patient files, all of the records in our possession. These are our patients. The issue to me again is fairness and I will say that on this particular item we do have a full time certificate for six days of service. The issue of one day versus ten days is irrelevant here. It is again incredibly unfair ….You are basically taking us out of business. I am not asking you for anything other than that you will allow us to stay in business. That is all we are asking…We are a national company and the statistics we gave you are more than reasonable. "

Dr. Paul Dreyer, responded briefly, "…If access doesn't mean need, then it is not a test that could ever be used because if it simply means geographic consideration, then anytime you move anything anyplace, you by definition are increasing access. It has to mean need. Otherwise it

has no meaning at all…" Dr. Sterne made a motion to accept staff recommendation of denial. The vote follows:

After consideration, upon motion made and duly seconded, it was voted: (Chair Ferguson, Mr. George, Jr., Ms. Slemenda, Dr. Sterne, and Dr. Williams in favor (Ms. Pompeo opposed; and Mr. Sherman and Mr. Thayer abstaining) [Ms. Cudmore absent] to deny the request by **Greater Boston Magnetic Resonance Imaging Limited Partnership** for a Transfer of Site of a Physician-Exempt, Fixed Mobile MRI Unit from Brockton, MA to a fixed-site MRI Unit in Norton MA., based on staff recommendation; and that a copy be attached and made a part of this record as **Exhibit Number 14,770.**

Chair Ferguson added, "I would like to have a short briefing before the Council on this whole issue, the evolution of 308 exemptions and where this is likely to occur again what rationale staff recommends."

The meeting adjourned at 12:30 p.m.

_____
Christine C. Ferguson, Chair
Public Health Council

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